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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,079

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Duane D. Blatter

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EXAMINER

EREZO, DARWIN P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,079	Applicant(s) BLATTER ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,8,26-31 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,26-31 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/16/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/09 has been entered.

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 4/13/09 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1, 28-31 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,485,513 to Fan and in view of US 6,063,114 to Nash et al.

Fan discloses a method for connecting a vessel **20** to another vessel **20'** (Fig. 7A, 7B) comprising: providing a synthetic graft vessel **10** having a first end and a second end, the second end coupled with a stent **9** such that portions of the stent are fixedly attached to the second end of the graft vessel (see Fig. 2); anastomosing the first end of the graft vessel to a side of an artery to yield an end-to-side anastomosis (Fig. 7A); inserting an introducer **30** into a vein; inserting a sheath **33** into the vein such that, when both the introducer and the sheath are in the vein, at least a portion of the introducer is within the sheath (Fig. 5, 6A); removing the introducer from the vein (Fig. 6B); inserting the second end of the graft vessel into the sheath such that at least a portion of the stent is within the vein (Fig. 6C); and removing the sheath from the vein such that the second end of the graft vessel is anastomosed to the vein via the stent to

yield an end-to-end anastomosis (Fig. 6D), wherein a first end of the stent is within the vein and a second end of the stent is outside the vein (as shown in Fig. 4); wherein when the sheath is removed from the vein, a perimeter length of the second end of the graft vessel remains substantially constant (the removal of the sheath in Fig. 6C keeps the graft vessel at the same location); wherein one end of the graft vessel will inherently be anastomosed first prior to the anastomosis of the other end; wherein the first end of the graft vessel is secured without suturing (Fig. 4).

Fan also discloses that the stent **9** is a self-expandable stent (col. 4, ll. 10-11) that is collapsed (compressed) prior to deployment (col. 3, ll. 40-42). In the deployed state, the stent has an outer diameter that is equal to or larger than the vein, in order to secure the stent against the interior lumen of the vein.

Fan is silent with regards to the step of inserting the second end of the graft vessel into the sheath after the introducer has been removed from the vein/sheath.

However, the step of using different tubular components during an anastomosis procedure is well known in the art, as disclosed by Nash. In Fig. 2, Nash discloses the step of inserting an introducer 44 and a sheath 42 in to a blood vessel. The introducer 44 is then removed from the sheath/vein, as seen in Fig. 7. The anastomosis connector is then introduced to the sheath after the removal of the introducer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Fan to include removing the introducer from the sheath prior to inserting the graft vessel into the vein because such steps are well known in the art, as taught by Nash. It has also been held that the use of a known technique to

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improve similar devices (anastomosis devices) in the same way will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). The modification to the methodology and device of Fan would merely require deploying the sheath 33 with the introducer 30, and using an additional deployment device, such as the one taught by Nash, with the graft vessel connector.

With regards to claim 29 and 30, Fan discloses the anastomosis of two vessels, as shown in Fig. 7A and 7B, but is silent with regards to the order of anastomosis. However, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to modify the methodology of Fan to either have the first end or the second end of the stent-graft to be anastomosed first since the sequence does not hold any criticality, especially since both ends will end up being anastomosed to their respective vessels.

7. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Nash et al., as applied to the claim 1 above, and in view of US 6,482,227 to Solovay.

The modified device of Fan discloses all the limitations of the claims except for the stent being fixedly attached to the graft via a polyurethane polymer glue. However, the use of a polyurethane glue is well known in the stent-graft art. For instance, Solovay discloses a graft **30** that is attached to a stent **12** via polyurethane glue (col. 6, ll. 62-67). Therefore, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to attach the stent to the graft

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via a polyurethane polymer glue since the use of said glue is well known in the art, as disclosed by Solovay.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Nash et al., as applied to the claim 1 above, and in view of US 6,428,550 to Vargas et al.

The modified device of Fan discloses all the limitation of the claim except for the stent being fixedly attached to the exterior surface of the graft vessel. However, Vargas discloses a similar stent-graft device, wherein the stent is fixedly attached to the exterior surface of the graft, as seen in Fig. 1. Therefore, the arrangement of the stent being located to the exterior surface of the graft is shown to be well known in the art and would be obvious to one of ordinary skill in the art. Furthermore, it would be obvious to have the stent be located on the outside of the graft instead of the inside since it has been held that a mere reversal of essential working parts of a device involves only routine skill in the art. *In re Gazda*, 219 F.2d, 449, 104 USPQ 400 (CCPA 1955).

Response to Arguments

9. Applicant's arguments filed 4/13/09 have been fully considered but they are not persuasive.

The amendment to claim 1 to include the limitation of “the stent defining an outer diameter” and “wherein the vein has an inner diameter equal to or smaller than the outer diameter of the stent” does not overcome the rejections over Fan in view of Nash et al. Fan discloses a self-expandable stent (col. 4, ll. 10-11) that is collapsed or compressed prior to deployment (col. 3, ll. 40-42). In the deployed state, the stent has an outer diameter that is equal to or larger than the vein, in order to secure the stent against the interior lumen of the vein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773